WHAT IS CLAIMED IS:

1. A composition useful for determining the presence of vitamin B12 in a sample, the composition comprising an antibody that is capable of specifically binding to intrinsic factor only in the absence of vitamin B12, and that is released from binding in the presence, and upon the binding, of vitamin B12 to intrinsic factor.

2. A kit for determining the presence of vitamin B12 in a sample, the kit comprising intrinsic factor and labelled antibody, the antibody being one which will specifically bind to the intrinsic factor in an amount related to the amount of vitamin B12 present in the sample, wherein the antibody is capable of binding to intrinsic factor only in the absence of vitamin B12, and is released from binding in the presence, and upon the binding, of vitamin B12 to intrinsic factor.

3. The kit of claim 2 further comprising a second antibody which will specifically bind to intrinsic factor without regard to the presence or absence of vitamin B12.

4. The kit of claim 3 wherein the second antibody is bound to a solid phase support.

5. A kit for assaying for vitamin B12 in a sample comprising (a) solid phase support to which is bound a predetermined amount of an antibody that is capable of specifically binding to intrinsic factor only in the absence of vitamin B12, and that is released from binding in the presence, and upon the binding, of vitamin B12 to intrinsic factor, and (b) a predetermined amount of a labelled intrinsic factor.

6. The kit of claim 5 wherein the label is alkaline phosphatase and further comprising a substrate to detect the presence or amount of the label.

7. A method of obtaining a monoclonal antibody capable of binding to intrinsic factor only in the absence of vitamin B12, and being released from binding in the presence, and upon the binding, of vitamin B12 to intrinsic factor, comprising the steps of:

a) immunizing an animal with substantially purified intrinsic factor;

b) isolating splenic lymphocytes from the immunized animal;

c) fusing the isolated splenic lymphocytes with a plasmocytoma cell line to obtain a plurality of hybridoma clones which secrete antibody;

d) extracting free vitamin B12 from a predetermined amount of culture supernatant containing antibody from each hybridoma clone;

e) contacting a first sample of each extracted antibody-containing supernatant with intrinsic factor in the presence of vitamin B12;

f) contacting a second sample of each extracted antibody-containing supernatant with intrinsic factor in the absence of vitamin B12;

g) contacting an enzyme labelled antibody which specifically binds to immunoglobulin with each of the first and second samples;

h) detecting the presence of labelled antibody present in each of the first and second samples; and

i) isolating the hybridomas which secrete antibodies which bound to intrinsic factor only in the absence of vitamin B12.

8 9. The method of claim 7 wherein the extraction step (d) is performed using dextran coated charcoal.

Rule 1.126

9 10. A diagnostic assay method for vitamin B12 in a liquid sample comprising:

(a) contacting the sample with a known amount of labelled intrinsic factor and a known amount of an antibody bound to a solid phase which specifically binds to intrinsic factor in an amount related to the presence or amount of vitamin B12 in the sample, said antibody being capable of binding to a site on intrinsic factor that is distinct from the site on intrinsic factor to which vitamin B12 binds and which binds to intrinsic factor only in the absence of vitamin B12, and that is released from of B12? binding in the presence, wherein the intrinsic factor will specifically bind to vitamin B12 in the sample to form a vitamin B12-intrinsic factor complex;

(b) separating the vitamin B12-intrinsic factor complex; and

(c) determining the amount of vitamin B12 by measuring the amount of label associated with the vitamin B12-intrinsic factor complex or the amount label bound to the antibody on the solid phase.

10 11. The method of claim 10 wherein the antibody is a monoclonal antibody.